HURLEY BROAD SPECTRUM SPF 50- avobenzone, homosalate, octisalate, octocrylene lotion Prime Enterprises Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

BASK Broad Spectrum SPF 50 Lotion

Active Ingredients

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 5%

Purpose

Sunscreen

Uses

- Helps prevent sunburn
- If used as directed with other sun protection measures (See **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings

For external use only

Do not use

on damaged or broken skin

When using this product

keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if

rash occurs.

Keep out of reach of children.

If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally 15 minutes before sun exposure.
- Reapply:
- After 80 minutes of swimming or sweating
- Immediately after towel drying
- At least every 2 hours
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:
- Limit time in the sun, especially from 10 a.m. 2 p.m.
- Wear long-sleeve shirts, pants, hats, and sunglasses.
- Children under 6 months: Ask a doctor.

Inactive Ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, C12-15 Alkyl Benzoate, Carbomer, Disodium EDTA, Ethylhexylglycerin, Fragrance, Hydroxypropyl Methylcellulose, Phenoxyethanol, Polyethylene, Polysorbate 20, Propylene Glycol, Sodium Hydroxide, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Water

Other Information

Protect the product in this container from excessive heat and direct sun

Questions or Comments?

Call(631) 800-7SPF(800-7773) or hello@basksuncare.com

Bask Broad Spectrum SPF 50 Lotion

Drug Facts

Active Ingredients

Purpose

Avobenzone 3%, Homosalate 10%,

Octisalate 5%, Octocrylene 5% Sunscreen

. Helps prevent sunburn + if used as directed with other sun protection measures (see Directions) decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings

For external use only . Do not use on damaged or broken skin

- When using this product keep out of eyes. Rinse with water to remove - Stop use and ask doctor if rash occurs - Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

- · Apply liberally 15 minutes before sun exposure
- · Reapply
- Reapply

 After 80 minutes of wiguring of Sating
- Immediately after towel drying
- At least every 2 hours
- Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including
 - Limit time in sun, especially 10am-2pm
- Wear long-sleeve shirts, pants, hats, and sunglasses
- · Children under 6 months: ask a doctor

Inactive Ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, C12-15 Alkyl Benzoate, Carbomer, Disodium EDTA, Ethylhexylglycerin, Fragrance, Hydroxypropyl Methylcellulose, Phenoxyethanol, Polyethylene, Polysorbate 20, Propylene Glycol, Sodium Hydroxide, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Water.

Other Information

· Protect the product in this container from excessive heat and direct sun

Ouestions or Comments

Call (631) 800-7SPF (800-7773) or hello@basksuncare.com

Distributed by Surfside Skincare, Inc. New York, NY 10010







SCAN TO REORDER

Basking in our purpose: a portion of proceeds from every purchase is contributed to skin cancer charities.











BROAD SPECTRUM SPF 50 LOTION

Water & Sweat Resistant (80 minutes) 3.4 FL OZ (100 ml)

HURLEY BROAD SPECTRUM SPF 50

avobenzone, homosalate, octisalate, octocrylene lotion

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Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:58443-0586

Route of Administration

TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZ ONE	29.19 g in 1 mL	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	48.65 g in 1 mL	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	48.65 g in 1 mL	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	97.3 g in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
COCOA BUTTER (UNII: 5120YT1CRR)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CARBOMER 980 (UNII: 4Q93RCW27E)	

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:58443- 0586-3	100 mL in 1 TUBE; Type 0: Not a Combination Product	06/13/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	06/13/2022	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0586) , manufacture(58443-0586) , label(58443-0586) , analysis(58443-0586)

Revised: 11/2022 Prime Enterprises Inc.